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10567594 - GAI: 1615

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10567594
	Filing Date		2006-12-12
	First Named Inventor	Elisabeth ARKENAU-MARIC, et al	
	Art Unit	TBA	
	Examiner Name	TBA	
	Attorney Docket Number	107101-47 WCG	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3806603		1974-04-23	Gaunt et al.	
	2	4744976		1988-05-17	Snipes et al	
	3	4764378		1988-08-16	Keith et al	
	4	4774074		1988-09-27	Snipes	
	5	4806337		1989-02-21	Snipes et al	
	6	5004601		1991-04-02	Snipes	
	7	7141250		2006-11-28	Oshlack et al	
	8	RE33093		1989-10-17	Schiraldi et al	

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9	4629621	1986-12-16	Snipes	
10	4713243	1987-12-15	Schiraldi et al	
11	4892778	1990-01-09	Theeuwes et al	
12	5200197	1993-04-06	Wright et al.	
13	6096339	2000-08-01	Ayer et al	
14	6340475	2002-01-22	Shell et al	
15	6488962	2002-12-03	Berner et al	
16	6534089	2003-03-18	Ayer et al	
17	6635280	2003-10-21	Shell et al	
18	6723340	2004-04-20	Gusler et al	
19	4404183	1983-09-13	Kawata et al	

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20	6436441	2002-08-20	Sako et al
21	5273758	1993-12-28	Royce
22	5945125	1999-08-31	Kim
23	6117453	2000-09-12	Seth et al
24	4070494	1978-01-24	Hoffmeister et al.
25	4612008	1986-09-16	Wong et al.
26	4765989	1988-08-23	Wong et al.
27	4783337	1988-11-08	Wong et al.
28	6248737	2001-06-19	Buschmann et al.
29	5801201	1998-09-01	Graudums et al.
30	3980766	1976-09-14	Shaw et al.

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	31	3966747		1976-06-29	Monkovic et al.	
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	1	20020051820		2002-05-02	Shell et al.	
	2	20030091630		2003-05-15	Louie-Helm et al.	
	3	20030104052		2003-06-05	Berner et al.	
	4	20030133985		2003-07-17	Louie-Helm et al.	
	5	20030152622		2003-08-14	Louie-Helm et al.	
	6	20040010000		2004-01-15	Ayer et al.	
	7	20040156899		2004-08-12	Louie-Helm et al.	
	8	20040185105		2004-09-23	Berner et al.	

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9	20040213848		2004-10-28	Li et al.	
10	20050106249		2005-05-19	Hwang et al.	
11	20050112067		2005-05-26	Kumar et al.	
12	20050266084		2005-12-01	Li et al.	
13	20060240110		2006-10-26	Klick et al.	
14	20070020335		2007-01-25	Chen et al.	
15	20070092573		2007-04-26	Joshi et al.	
16	20070196396		2007-08-23	Pilgaonkar et al.	
17	20050031546		2005-02-10	Bartholomaeus et al.	
18	20060193914		2006-08-31	Ashworth et al.	
19	20070048228	A1	2007-03-01	ARKEN AU-MARIC ET AL.	

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FOREIGN PATENT DOCUMENTS

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	1	0 008 131	EP		1980-02-20	Union Carbide Corporation		<input type="checkbox"/>
	2	0 216 453	EP		1987-04-01	Fidia S.P.A.		<input type="checkbox"/>
	3	0 226 061	EP		1987-06-24	Allied-Signal Inc.		<input type="checkbox"/>
	4	0 228 417	EP		1987-07-15	ICI Australia Limited		<input type="checkbox"/>
	5	0 277 289	EP		1988-08-10	Biopure Corporation		<input type="checkbox"/>
	6	0 293 066	EP		1988-11-30	Alza Corporation		<input type="checkbox"/>
	7	0 328 775	EP		1989-08-23	Carrington Laboratories Inc.		<input type="checkbox"/>
	8	0 583 726	EP		1994-02-23	Kali-Chemie Pharma GmbH		<input type="checkbox"/>
	9	0 661 045	EP		1995-07-05	Yamanouchi Pharmaceutical Co. Ltd.		<input type="checkbox"/>

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10	0 696 598	EP		1996-02-14	Fidia Farmaceutici S.p.A.	<input type="checkbox"/>
11	1 859 789	EP		2007-11-28	Gruenenthal GmbH	<input type="checkbox"/>
12	0 232 877	EP		1987-08-19	Zetachron, Inc.	<input type="checkbox"/>
13	0 598 606	EP		1994-05-25	Johnson & Johnson Consumer Products, Inc.	<input type="checkbox"/>
14	94 06414	WO		1994-03-31	Yamanouchi Pharmaceutical Co. Ltd/	<input type="checkbox"/>
15	95 30422	WO		1995-11-16	Pfizer Inc.	<input type="checkbox"/>
16	96 00066	WO		1996-01-04	Alza Corporation	<input type="checkbox"/>
17	03 105808	WO		2003-12-24	Gruenenthal GmbH	<input type="checkbox"/>
18	2005 041968	WO		2005-05-12	Alza Corporation	<input type="checkbox"/>
19	2006 002883	WO		2006-01-12	Gruenenthal GmbH	<input type="checkbox"/>
20	2006 002884	WO		2006-01-12	Gruenenthal GmbH	<input type="checkbox"/>

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21	2006 082097	WO		2006-08-10	Gruenenthal GmbH	<input type="checkbox"/>
22	2006 082099	WO		2006-08-10	Gruenenthal GmbH	<input type="checkbox"/>
23	2007 008752	WO		2007-01-18	Farnam Companies, Inc	<input type="checkbox"/>
24	2007 048233	WO		2007-05-03	Orbus Pharma Inc.	<input type="checkbox"/>
25	2007 053698	WO		2007-05-10	Alza Corporation	<input type="checkbox"/>
26	02 26928	WO		2002-04-04	The Dow Chemical Company	<input type="checkbox"/>
27	90 03776	WO		1990-04-19	Zetachron, Inc.	<input type="checkbox"/>
28	93 11749	WO		1993-06-24	Warner-Lambert Company	<input type="checkbox"/>
29	03 035029	WO		2003-05-01	Depomed, Inc.	<input type="checkbox"/>
30	2005 016314	WO		2005-02-24	Gruenenthal GmbH	<input type="checkbox"/>
31	2005 063214	WO		2005-07-14	Gruenenthal GmbH	<input type="checkbox"/>

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32	2005 102286	WO		2005-11-03	Gruenenthal GmbH	<input type="checkbox"/>
33	10336400	DE	A1	2005-03-24	Grünenthal GmbH	<input type="checkbox"/>
34	2502965	CA	A1	2004-05-06	Grünenthal GmbH	<input type="checkbox"/>
35	2004 026263	WO	A2	2004-04-01	FMC Corporation	<input type="checkbox"/>
36	2003 01476	WO	A1	2003-01-03	Leapfrog Enterprises, Inc.	<input type="checkbox"/>
37	2530563	DE		1977-01-27	Bayer AG	<input type="checkbox"/>
38	199932120	WO		1999-07-01	Euro-Celtique, S.A.	<input type="checkbox"/>
39	2003 015531	WO	A2	2003-02-27	GRUBER	<input type="checkbox"/>
40	1995 20947	WO	A1	1995-08-10	RHONE-POULENC RORER LIMITED	<input type="checkbox"/>
41	2000 033835	WO	A1	2000-06-15	SANOFI-SYNTHELABO	<input type="checkbox"/>

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NON-PATENT LITERATURE DOCUMENTS

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	V.K. THOMA et al., "Bestimmung der In-vitro-Freigabe von schwach basischen Wirkstoffen aus Retardarzneiformen," Pharm. Ind. 51, Nr. 3 (1989)	<input type="checkbox"/>
	2	F. E. BAILEY et al., "Some Properties of Poly(ethylene oxide)' in Aqueous Solution," Journal of Applied Polymer Science, Vol. 1, Issue No. 1, pages 56-62 (1959)	<input type="checkbox"/>
	3	A. APICELLA et al., "Poly(ethylene oxide) (PEO) and different molecular weight PEO blends monolithic devices for drug release," Biomaterials 1993, Vol. 14, No. 2, pp. 83-90	<input type="checkbox"/>
	4	S. JANICKI et al., "Slow-Release Microballs: Method of Preparation," Acta Pharm. Technol. 33(3) 154-155 (1987)	<input type="checkbox"/>
	5	R. MANK et al., "Darstellung wirkstoffhaltiger Extrusionsformlinge auf der Basis von Thermoplasten," Pharmazie 45 (1990), H. 8; pp. 592-593	<input type="checkbox"/>
	6	R. MANK et al., "Darstellung wirkstoffhaltiger Extrusionsformlinge auf der Basis von Thermoplasten," Pharmazie 44 (1989) H. 11; pp. 773-776	<input type="checkbox"/>
	7	P. SHIVANAND et al., "Factors Affecting Release of KCl from Melt Extruded Polyethylene Disks," Pharmaceutical Research, Official Journal of the American Association of Pharmaceutical Scientists; October 1991, Vol. 8, No. 10	<input type="checkbox"/>
	4	Inert Gas from Wikipedia (December 2009)	<input type="checkbox"/>
	9	Dow Excipients Chemistry of Polyox Water Soluble-Resins	<input type="checkbox"/>
	10	M.M. CROWLEY et al., "Stability of polyethylene oxide in matrix tablets prepared by hot-melt extrusion," Biomaterials 23 (2002) 4241-4248	<input type="checkbox"/>

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11	M. EFENTAKIS et al., "Evaluation of High Molecular Weight Poly(Oxyethylene) (Polyox) Polymer: Studies of Flow Properties and Release Rates of Furosemide and Captopril from Controlled-Release Hard Gelatin Capsules," Pharmaceutical Development and Technology, 5(3), 339-346 (2000)	<input type="checkbox"/>
12	N. FOLLONIER et al., "Various ways of modulating the release of diltiazem hydrochloride from hot-melt extruded sustained release pellets prepared using polymeric materials," Journal of Controlled Release 36 (1995) 243-250	<input type="checkbox"/>
13	N.B. GRAHAM, "Poly(Ethylene Glycol) Gels and Drug Delivery," Poly(Ethylene Glycol) Chemistry: Biotechnical and Biomedical Applications, Chapter 17, 1992	<input type="checkbox"/>
14	C. D. HANNING et al., "The Morphine Hydrogel Suppository," British Journal of Anaesthesia, 1988, 61, 221-227	<input type="checkbox"/>
15	KIM et al., "Preparation and Evaluation of Eudragit Gels V. Rectal Gel Preparations for Sustained Release and Avoidance of First-Pass Metabolism of Lidocaine," Chem. Pharm. Bull. 40(10) 2800-2804 (1992)	<input type="checkbox"/>
16	CHERNG-JU KIM, "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," Journal of Pharmaceutical Sciences, Vol. 84, No. 3, March 1995	<input type="checkbox"/>
17	S.L. MADORSKY et al., "Thermal Degradation of Polyethylene Oxide and Polypropylene Oxide," Journal of Polymer Science, Vol. XXXVI, pages 183-194 (1959)	<input type="checkbox"/>
18	A. MORONI et al., "Application of Poly(Oxyethylene) Homopolymers in Sustained Release Solid Formulations," Drug Development and Industrial Pharmacy, 21(12), 1411-1428 (1995)	<input type="checkbox"/>
19	N. OHNISHI et al., "Effect of the Molecular Weight of Polyethylene Glycol on the Bioavailability of Indomethacin Sustained-Release Suppositories Prepared with Solid Dispersions," Chem. Pharm. Bull., 35 (8) 3511-3515 (1987)	<input type="checkbox"/>
20	T. OZEKI et al., "Control of medicine release from solid dispersion composed of the poly(ethylene oxide)-carboxyvinylpolymer interpolymers by varying molecular weight of poly(ethylene oxide)," Journal of Controlled Release 58 (1999) 87-95	<input type="checkbox"/>
21	Pharmaceutical Research, Official Journal of the American Association of Pharmaceutical Scientists, September 1989 (Supplement), Vol. 6, No. 9, 6.S-98	<input type="checkbox"/>

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22	Pharmaceutical Research, Official Journal of the American Association of Pharmaceutical Scientists, October 1991 (Supplement), Vo. 8, No. 10, 8.S-192	<input type="checkbox"/>
23	W. PRAPAITRAKUL et al., "Release of Chlorpheniramine Maleate from Fatty Acid Ester Matrix Disks Prepared by Melt-extrusion," J. Pharm. Pharmacol. 1991, 43: 377-381	<input type="checkbox"/>
24	S. RADKO et al., "Molecular sieving by polymer solutions: dependence on particle and polymer size, independence of polymer entanglement," Applied and Theoretical Electrophoresis (1995), 5, 79-88	<input type="checkbox"/>
25	J. SCHEIRS et al., "Characterizing the solid-state thermal oxidation of poly(ethylene oxide) powder," Polymer, 1991, Volume 32, Number 11	<input type="checkbox"/>
26	O.L. SPROCKEL et al., "Permeability of Cellulose Polymers: Water Vapour Transmission Rates," J. Pharm. Pharmacol. 1990, 42: 152-157	<input type="checkbox"/>
27	J.L. STRINGER et al., "Diffusion of small molecular weight drugs in radiation-crosslinked poly(ethylene oxide) hydrogels," Journal of Controlled Release 42 (1996) 195-202	<input type="checkbox"/>
28	E. G. RIPPIE et al., "Regulation of Dissolution Rate by Pellet Geometry," Journal of Pharmaceutical Sciences, Vo. 58, No. 4, April 1969, pp. 428-431	<input type="checkbox"/>
29	M. ADEL EL-EGAKEY et al., "Hot extruded dosage forms Part I," Pharmaceutica Acta Helvetiae, Vol. 46, March 19, 1970	<input type="checkbox"/>
30	Remington's Pharmaceutical Sciences 17th ed., Mack Publishing Co., (1985) 1418	<input type="checkbox"/>
31	M.S. MESIHA et al., "A Screening Study of Lubricants in Wet Powder Masses Suitable for Extrusion Spheronization," Drug Development and Industrial Pharmacy, 19(8), 943-959 (1993)	<input type="checkbox"/>
32	N. FOLLONIER et al., "Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules Containing High Loadings of Freely Soluble Drugs," Drug Development and Industrial Pharmacy, 20(8), 1323-1339 (1994)	<input type="checkbox"/>

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33	Remington's Pharmaceutical Sciences, Authur Asol editor, pages 1553-1593, Chapter 89, 1980.	<input type="checkbox"/>
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